

REMARKS

Applicant respectfully traverses the § 102(b) rejection of claims 1, 12, and 13 over Mathiasen '506 and Kaufman '589.

The present invention relates to an inserter for a low-profile angled infusion set. A retainer housing has a distal end with an opening. A retainer is slidably mounted in the retainer housing. An infusion set can be releasably attached to the retainer. The infusion set includes a cannula and an insertion needle, which cooperate to define an insertion axis. The retainer is moved from a retracted position to an extended position by movement of a tension spring, which is expanded when the retainer is retracted, and contracts to bias the retainer to its extended position. The spring is released from its expanded position by pressing a first release button. This button is positioned on the inserter housing proximate the distal end, and when it is pressed downward, it moves in a line that is substantially normal to the insertion axis. A base member is connected to the bottom wall of the inserter housing, proximate the opening in the distal end. The base member defines an acute angle with respect to the bottom surface of the inserter housing, so that when it is placed against a user's skin, the base positions the insertion axis of the needle and cannula at the acute angle with respect to the skin. When the first release button is pressed, the retainer is extended and the needle and cannula are guided to be inserted subcutaneously in the skin at the acute angle.

The position of the base member, and the acute angle defined by the base member, serve to guide the needle and the cannula to be injected at the acute angle under the bias of the contracting tension spring, so the needle and cannula should always be inserted at the same acute angle. The position of the button, proximate the distal end of the housing, and application of force to the button in a direction that is

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normal to the injection axis helps maintain stability of the apparatus during injection of the needle into the skin, because the inserter housing is not subjected to a severe torque, as it would be if the button were positioned at the other end of the inserter housing.

The claims have been amended to more clearly reflect the features of the invention described above.

Mathiasen, in contrast, does not disclose insertion of a needle 18, or a cannula 2. Although Fig. 3 appears to show the cannula 2 extended at an angle created by the pivoting upward of housing 1 relative to base 8. There also is no teaching whatsoever of any structure to guide the cannula 2 for insertion into the skin at an acute angle. There also is no disclosure of a spring for biasing a retainer that is releasably holding an infusion set, and no disclosure of a release button proximate the distal end and movable in a direction normal to an axis defined by the cannula 2 and needle 15. Lacking at least these teachings, Mathiasen cannot anticipate the claims of the present invention.

Kaufman '589 likewise lacks the above teachings. Kaufman discloses a spring 28. Spring 28 is compressed when the Kaufman carrier is moved forward under manual force for insertion (col. 6, line 63). Spring 28 is later released/expanded to move the Kaufman carrier back under the spring force back to the retracted position. See col. 7, lines 24-35 and Fig. 6. The Kaufman spring, therefore, expands to retract the needle, and is compressed when the needle is inserted; and needle insertion is not performed with the assistance of spring bias, but rather, against spring bias. Hence, the Kaufman spring is both configured differently, and functions differently from the tension spring of the invention. Kaufman also discloses no release button for releasing the retainer to

move to its extended position, and has no need for such a button. The Kaufman needle is extended under manual force (col. 6, line 63), and because the Kaufman needle is inserted manually, without benefit of contraction of a tension spring, there is no need for a first release button, as claimed, and so Kaufman cannot anticipate the stability provided by the claimed location and mode of operation of the claimed first release button. Lacking at least these features of the claimed invention, Kaufman cannot anticipate the claims.

Applicant also respectfully traverses the § 103(a) rejection of claims 1, 2, 3, 5, 6, 7, 8, 9, 12, 13, 14, and 15 over Clement in view of Mathiasen or Kaufman, and the § 103(a) rejection of claims 1-16 over Clement, Mathiasen, Kaufman, and Bogart.

Clement discloses a biopsy needle instrument. It has no base defining an acute angle, for guiding a needle and a cannula during insertion. The needle and cannula in Clement remain in the housing; they are not part of an infusion set that can be releasably mounted in a movable retainer. The release button in Clement is not provided proximate the distal end with the opening, and is not pressed in a direction normal to an insertion axis defined by the needle and cannula, because the Clement device has no need for the guided insertion angle, or the additional stability of the present invention. Therefore, Clement cannot provide the teachings that are missing from Mathiasen or Kaufman, and so these patents, alone or in combination, cannot render obvious the present claims.

Entry of this amendment under Rule 116 is proper in order to place the case in condition for allowance or in order to reduce the issues on appeal. Applicant

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respectfully requests entry of the amendment, reconsideration, withdrawal of the rejections, and a prompt Notice of Allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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